



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 083478 0024 Rev. 01

Manufacturer

**Zhejiang Longterm
Medical Technology Co., Ltd.**

Huancheng North Road 493

Mo Gan Mountain

National High-Tech District

313200 Deqing, Zhejiang

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, THE

NETHERLANDS

Product Category(ies):

**Medical Tapes, Surgical Drapes, Infusion Plasters,
Equipment Cover, Skin Closure Strips, Sterile
Wound Plasters, Sterile Wound Dressing, Ostomy
Bags and Accessories, Catheter Fixing Dressing,
Hydrogel Eye Pad, Urostomy Bag, Urinary Collection
Bag, Compression Hemostatic Dressing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1978208

Valid from: 2019-03-30

Valid until: 2023-04-22

Date, 2019-03-30

Stefan Preiß

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 083478 0024 Rev. 01

Facility(ies):

Zhejiang Longterm Medical Technology Co., Ltd.
Huancheng North Road 493, Mo Gan Mountain, National High-
Tech District, 313200 Deqing, Zhejiang, PEOPLE'S REPUBLIC OF
CHINA



Certificate

No. Q5 083478 0025 Rev. 00

Holder of Certificate: **Zhejiang Longterm Medical Technology Co., Ltd.**
Huancheng North Road 493
Mo Gan Mountain
National High-Tech District
313200 Deqing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Hydrocolloid dressing, Alginate dressing, Foam dressing and Silicone foam dressing, Hydrogel dressing, Absorbent dressing, Negative pressure wound therapy dressing, Silicone net, NPWT silicone foam dressing
Production and Distribution of Sterile wound dressing, Skin closure strips, Surgical drapes, Fecal collection bags, Sterile wound plasters, Scar reducing emollient, Ostomy bags and attachments, Infusion plasters, Urinary drainage bag/collection bag, Silicone tapes and Medical external fixation, Medical tapes, Hydrocolloid patch, Equipment cover, Sterile Hydrocolloid dressing, Catheter Fixing Dressing, Hydrogel Eye Pad, Urostomy Bag, Urinary Collection Bag, Compression Hemostatic Dressing, Wound Drainable Bag

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1978208

Valid from: 2019-04-01

Valid until: 2022-03-31

Date, 2019-03-30

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

Certificate

No. Q5 083478 0025 Rev. 00

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): Zhejiang Longterm Medical Technology Co., Ltd.
 Huanheng North Road 493, Mo Gan Mountain, National High-
 Tech District, 313200 Deqing, Zhejiang, PEOPLE'S REPUBLIC OF
 CHINA

Parameters:

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT